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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,848	08/21/2003	Mark Chee	ILLINC.043DV1	5268

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,848	CHEE ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 25* is/are rejected.

7)☒ Claim(s) *24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Remark

Preliminary Amendment received on August 21, 2003, canceling claims 1-23 and 26 is acknowledged.

Claims 24 and 25 are pending and are under prosecution therefore.

Information Disclosure Statement

The IDS received on December 22, 2003 is acknowledged.

A signed copy of the PTO-1449 is enclosed herewith.

Drawings

The drawings received on August 21, 2003 are acceptable.

Claim Objections

Claims 24 and 25 are objected to because of the following informalities:

a) claim 24 contains a grammatical error in step (b)(ii), in the phrase, "a least one decoding nucleotide." The phrase should read, "at least one decoding nucleotide."

b) claim 25, between steps (d)(i) and (d)(ii), should contain a conjunction, "and."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 25 are indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, claims 24 and 25 are drawn to a method of decoding an array composition, yet the claims recite a final step detecting the presence of a label. The claims do not set forth the conditions/state when the method has been completed [i.e., needs to agree with preamble].

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Walt et al. (WO 98/40726, published September 17, 1998; IDS ref# B16).

Walt et al. disclose a method of decoding an array composition comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites (see Figure 5A for example; page 7, lines 5-9); and

ii) a population of microspheres (see Figure 5B for example; page 5, line 25; page 6, line 1) comprising at least a first and a second subpopulation distributed on said discrete sites (page 6, lines 1-2; page 7, lines 10-11; page 17, lines 13-17 for discussion of three subpopulations), wherein each subpopulation comprises an identifier nucleic acid sequence (page 16, line 28 through page 17, line 12 and Table V for the discussion of probe and target nucleic acid sequence) comprising:

1) a primer sequence; and

2) a decoding sequence adjacent to said primer sequences.

Walt et al. disclose that the probe sequence immobilized on the microspheres comprises a string of nucleotide sequences comprising a sequence which is complementary to the sequence of the target nucleic acid sequence. Since the instant specification lacks a specific definition regarding what is considered to be a primer sequence and what is considered to be a decoding sequence, a string of nucleotides of the probe would necessarily anticipate this limitation.

Walt et al. disclose that that the microspheres are distributed on the surface (page 7, lines 5-12, in the phrase, "each one of the beads is located within separate wells formed at the terminal side of the optical fibers of the bundle.").

The method disclosed by Walt et al. disclose that this array composition is employed in a hybridization assay (for the genosensor embodiment; see page 17), wherein the probe sequence comprising both the primer sequence and decoding sequence is hybridized to the target nucleic acid sequence (see the complementarity of the probe and target sequence (or a first probe) for IFNG detection in Table V, page 17).

The target nucleic acid (or a first decoding probe) is labeled on its 5' end with a fluorescein label (Table V, page 17).

The pattern of the target nucleic acid hybridization is detected and decoded (page 6, lines 14-18), thereby clearly anticipating instant claim 24.

With regard to claim 25, the artisans are explicit in that the array composition comprises multiple subpopulation, each subpopulation of which is drawn to a different target analyte (page 17, lines 15-17; page 18, line 5 through page 19, line 2; see also pages 24-25 for detection of different analytes involving microsphere comprising different probes).

Therefore, the invention as claimed is clearly anticipated by Chee et al.

Claims 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al. (U.S. Patent No. 6,023,540, issued February 8, 2000, filed March 14, 1997; IDS ref# A54).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that **any invention disclosed but not claimed** in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants are explicitly advised that the prior art **is claiming** the same invention and thus, the showing under 37 CFR 1.132 will **not** be sufficient to overcome the instant rejection.

Walt et al. disclose a method of decoding an array composition comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites (see Figure 5A for example; column 4, lines 4-6); and

ii) a population of microspheres (see Figure 5B for example; column 4, lines 4-6; column 11, lines 31-34; column 12, line 10) comprising at least a first and a second subpopulation distributed on said discrete sites (column 3, lines 33-35; column 10, lines 42-45, for discussion of three subpopulations), wherein each subpopulation comprises an identifier nucleic acid sequence (column 10, lines 4-17 and Table V for the discussion of probe and target nucleic acid sequence) comprising:

1) a primer sequence; and

2) a decoding sequence adjacent to said primer sequences.

Walt et al. disclose that the probe sequence immobilized on the microspheres comprises a string of nucleotide sequences comprising a sequence which is complementary to the sequence of the target nucleic acid sequence. Since the instant specification lacks a specific definition regarding what is considered to be a primer sequence and what is considered to be a decoding sequence, a string of nucleotides of the probe would necessarily anticipate this limitation.

Walt et al. disclose that that the microspheres are distributed on the surface (column 4, lines 4-6, in the phrase, "each one of the beads is located within separate wells formed at the terminal side of the optical fibers of the bundle.").

The method disclosed by Walt et al. disclose that this array composition is employed in a hybridization assay (for the genosensor embodiment; see column 10), wherein the probe sequence comprising both the primer sequence and decoding sequence is hybridized to the target nucleic acid sequence (see the complementarity of the probe and target sequence (or a first probe) for IFNG detection in Table V, column 10).

The target nucleic acid (or a first decoding probe) is labeled on its 5' end with a fluorescein label (Table V).

The pattern of the target nucleic acid hybridization is detected and decoded (column 10, lines 4-41; and claims 1, 39, 49, and 50), thereby clearly anticipating instant claim 24.

With regard to claim 25, the artisans are explicit in that the array composition comprises multiple subpopulation, each subpopulation of which is drawn to a different target analyte (column 10, line 41 through column 11, line 14; see also column 13, line 47 through column 14, line 58 for detection of different analytes involving microsphere comprising different probes).

Therefore, the invention as claimed is clearly anticipated by Chee et al.

Claims 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al. (U.S. Patent No. 6,266,459, issued July 24, 2001, priority March 14, 1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that **any invention disclosed but not claimed** in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants are explicitly advised that the prior art **is claiming** the same invention and thus, the showing under 37 CFR 1.132 will **not** be sufficient to overcome the instant rejection.

Walt et al. disclose a method of decoding an array composition comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites (see Figure 5A for example; column 4, lines 11-13); and

ii) a population of microspheres (see Figure 5B for example; column 4, lines 11-13; column 11, lines 42-45; column 12, line 28) comprising at least a first and a second subpopulation distributed on said discrete sites (column 3, lines 40-42; column 10, lines 52-56, for discussion of three subpopulations), wherein each subpopulation comprises an identifier nucleic acid sequence (column 10, lines 12-51 and Table V for the discussion of probe and target nucleic acid sequence) comprising:

1) a primer sequence; and

2) a decoding sequence adjacent to said primer sequences.

Walt et al. disclose that the probe sequence immobilized on the microspheres comprises a string of nucleotide sequences comprising a sequence which is complementary to the sequence of the target nucleic acid sequence. Since the instant specification lacks a specific definition regarding what is considered to be a primer sequence and what is considered to be a decoding sequence, a string of nucleotides of the probe would necessarily anticipate this limitation.

Walt et al. disclose that that the microspheres are distributed on the surface (column 4, lines 11-13, in the phrase, "each one of the beads is located within separate wells formed at the terminal side of the optical fibers of the bundle.").

The method disclosed by Walt et al. disclose that this array composition is employed in a hybridization assay (for the genosensor embodiment; see column 10), wherein the probe sequence comprising both the primer sequence and decoding sequence is hybridized to the target nucleic acid sequence (see the complementarity of the probe and target sequence (or a first probe) for IFNG detection in Table V, column 10).

The target nucleic acid (or a first decoding probe) is labeled on its 5' end with a fluorescein label (Table V).

The pattern of the target nucleic acid hybridization is detected and decoded (column 10, lines 12-51; and claims 1 and 10), thereby clearly anticipating instant claim 24.

With regard to claim 25, the artisans are explicit in that the array composition comprises multiple subpopulation, each subpopulation of which is drawn to a different target analyte (column 10, line 12 through column 11, line 12; see also column 13, line 59 through column 14, line 67 for detection of different analytes involving microsphere comprising different probes).

Therefore, the invention as claimed is clearly anticipated by Chee et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, and 39-53 of U.S. Patent No. 6,023,540 (herein

the '540 patent; IDS ref# A54). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The '540 patent discloses a method of detecting target analytes, the analytes of which is a nucleic acid (see claims 49 and 50), wherein the method involves an array composition comprising a substrate with a plurality of wells (thus comprising discrete sites; see claim 1 for the term, "system," and claims 9-10 for the description of the system), each well comprising a population of microspheres, said population comprising "subpopulations" (claim 1), wherein each subpopulation comprises an identifier nucleic acid (claims 39 and 50), the identifier nucleic acid comprising nucleotide sequence which hybridizes to a target sequence (claim 49).

Sine the instant specification lacks a specific definition regarding what is considered to be a primer sequence and what is considered to be a decoding sequence, a string of nucleotides of the probe (of the '540 patent) would necessarily meet this limitation.

Claim 1 of the '540 patent recites that the claimed system is applied to detect the changes in the optical signatures of the beads (or microspheres), wherein claims 39, 49, and 50 necessarily require that the target nucleic acid and the probe of the microsphere hybridize (see also claim 8 of the '540 patent) to each other (basepairing), thereby clearly rendering instant claim 24 obvious.

With regard to instant claim 25, column 10, lines 50-67 renders clear that multiple analytes are detected on the disclosed system, wherein the disclosed invention allows decoding of the different analytes, rendering instant claim 25 obvious.

Therefore, the invention as claimed is obvious over claims 1-16, and 39-53 of the '540 patent.

Claims 24 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,266,459 (herein the '459 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The '459 patent discloses a method of detecting target analytes, the analytes of which is a nucleic acid (see claim 10), wherein the method involves an array composition comprising a substrate with a surface (thus comprising discrete sites), said surface comprising a population of beads (or microspheres), said population comprising "subpopulations" (claim 1), wherein each subpopulation comprises an chemical functionality, the chemical functionality being oligonucleotide (claim 10) which comprises nucleotide sequence which hybridizes to a target sequence.

Sine the instant specification lacks a specific definition regarding what is considered to be a primer sequence and what is considered to be a decoding sequence, a string of nucleotides of the probe (of the '459 patent) would necessarily meet this limitation.

Claim 1 of the '459 patent recites that the claimed system is applied to detect the changes in the optical signatures of the beads (or microspheres), wherein claim 10 necessarily requires that the target nucleic acid and the oligonucleotide of the microsphere hybridize to each other (basepairing), thereby clearly rendering instant claim 24 obvious.

With regard to instant claim 25, column 10, lines 65-67 render clear that multiple analytes are detected on the disclosed system, wherein the disclosed invention allows decoding of the different analytes, rendering instant claim 25 obvious.

Therefore, the invention as claimed is obvious over claims 1-21 of the '459 patent.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner YOUNG J. KIM
Art Unit 1637 PATENT EXAMINER
1/21/2006

yjk